



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,030	05/25/2001	Ragbir S. Bhullar	RDID 0090 US	4269
32842	7590	05/26/2005	EXAMINER	
THE LAW OFFICE OF JILL L. WOODBURN, L.L.C. JILL L. WOODBURN 128 SHORE DR. OGDEN DUNES, IN 46368			SIEFKE, SAMUEL P	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,030	BHULLAR ET AL.	
	Examiner	Art Unit	
	Samuel P. Siefke	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/11/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,10-15,21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,10-15 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). _____
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6,10-15,21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are pointed out individually below.

Claim 24: "a support having first and second ends" it is unclear to define an end on a support that has 6 sides (flat support: top side, bottom side, left side, right side, upper surface, lower surface) Claim 24: "and electrode array", it is unclear to define two pair of electrodes and call it an array.

Claim 24: "a spacer having individual members" is unclear. Claim 2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers.

Claim 24: "a cover cooperating with support to define a capillary channel extending between the individual members" The cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this.

Claim 24: "the channel having opposite ends" It is unclear and indefinite to claim a channel having opposite ends. Where does a channel end?

Claim 24: "a concave inlet extending from the first end of the support and being positioned between opposite ends of the channel" It is unclear and indefinite to claim a concave inlet extending from a first end, what first end? Where on the support? The applicant needs to define the positioning and orientation of the inlet with respect to the channel that is defined by the support, cover and two spacers. The inlet is the channel?

Claim 24: "each electrode array being positioned in the channel adjacent to one of the opposing ends" What opposing ends? Adjacent to what? The electrode arrays are just two electrodes connected to each other to make a couple or pair of electrodes not an array.

Claim 25: "a support having first edge" It is unclear to define an edge on a support that has 6 sides (flat support: top side, bottom side, left side, right side, upper surface, lower surface).

Claim 25: "first and second electrode sets positioned on the support spaced apart from one another" Where on the support and what orientation are the electrodes related to each other. It is unclear and indefinite.

Claim 25: "a spacer having individual members" is unclear. Claim 2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers.

Claim 25: "a cover having a second edge and extending across the first and second electrode sets," A cover has multiple edges, like a substrate defined above. It is unclear and indefinite to claim an edge on a cover. It is more than likely that the edge

is not extended across the first and second electrode, it would be a plane of the cover and not an edge.

Claim 25: "the cover cooperating with support to define a generally linear capillary channel extending between the individual members" The cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this. A generally linear channel is unclear and indefinite.

Claim 25: "the channel having opposing first and second ends and an inlet aligned with the first edge of the support and the second edge of the cover" How does a channel have opposing first and second ends if it is not a totally closed channel, sounds more like a chamber, it is unclear and indefinite. First edge of the support and the second edge of the cover is unclear and indefinite, where are the spacers in this orientation?

Claim 25: "between the ends of the channel" What is this referring to?

Claim 25: "and between the first and second electrode sets" again what is this referring to, it is unclear and indefinite.

The biosensor needs to show communication between each object in a clear and concise manner in which one of ordinary skill in the art would be able to have a clear understanding of invention.

Claim 26 has the same problems as mentioned in claim 24 and claim 25. It is entirely unclear and indefinite as a whole.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **6,10-15,21-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nankai (USPN 5,120,420).

Nankai teaches a biosensor that comprises a support substrate (1), electrodes positioned on the support substrate (2,3,3') and electrode system (4,5,5'), an insulating layer (6), a reaction layer (14) composed of an enzyme and an electron acceptor and being provided thereon with a space (8, channel) defined by a spacer (7) with members (fig.4 U shaped), an a cover (9). When the support substrate, spacer and members, and cover are sandwiched together a channel (8) is formed (fig. 4-6). When a biological sample solution is brought into contact with the inlet (10) of the biosensor, the sample solution is introduced into its insides through inlet (10) wherein the sample fills the

space (8). With regards to claim 4-6, the claims only require that the spacer have members. The broadest possible reading on this would be a spacer layer that has members formed from an original spacer (fig.4). In Fig. 4, there is a U shaped spacer. The base part of the U would be member 1, the left part of the U would be member 2, and the right part of the U would be member 3. Claim 6 requires that a the second and third members are spaced apart, Fig 4 shows this configuration and further a channel (8) extends between the first, second, and third members. Fig 12 shows further embodiments of the spacer layer and multiple members to create multiple channels.

Nankai does not teach a T-shaped channel defined by a cover and a support substrate. With regards to the T-shaped channel, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape of the channel. The change in shape is to allow the sample flow to be directed to different electrodes (see fig. 12). (Changes of size, degree, shape proportion, and sequence of adding ingredients – In re Rose, 105 U.S.P.Q. 237; In re Aller et al., 105 U.S.P.Q. 233; In re Daily et. al., 149 U.S.P.Q. 47; In re Reese, 129 U.S.P.Q. 402; In re Gibson, 45 U.S.P.Q. 284.).

Response to Arguments

Applicant's arguments filed 4/11/05 have been fully considered but they are not persuasive. The claim language Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or

she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Applicant argues, "Regarding claim 24, Applicants ignored Nankai teaching of the port (10) at the end of the space (8) and taught instead that it (sp.) biosensor comprise a channel having opposing ends and a concave inlet extending from the first end of the support an being positioned between the opposing ends of the channel. None of the illustrations of Nankai port (10) provide such a configuration." Nankai teaches each and ever limitation set for in the independent claims 24, 25 and 26. Claim 24, 25 and 26 are rejected under 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues, "there is no motivation in the cited reference to modify the spacer (7) as taught by Nankai to meet the requirements of the biosensor as defined by claim 24." This argument is applied to claim 25 and 26, so all three will be addressed together. The case law applied in the rejection states that it would have been obvious to one having an ordinary skill in the art to change the shape of an object. The spacer of Nankai performs the same function of the spacer in the instant application, it provides 2 sides of a channel in which a fluid flows there through, the other sides of the channel are provided by the cover and the substrate.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

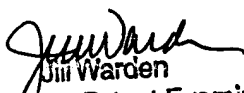
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



May 11, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700